Contains Nonbinding Recommendations

Draft Guidance on Repaglinide

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Repaglinide

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two way crossover *in-vivo*
   Strength: 2 mg
   Subjects: Normal healthy males and females, general population
   Additional comments: To avoid hypoglycemic episodes in healthy volunteers, the drug products should be administered with 240 mL of 20% aqueous glucose solution, followed by 60 ml of the glucose solution administered every 15 minutes for up to 4 hours after dosing.

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2. Type of Study: Fed
   Design: Single-dose, two way crossover *in-vivo*
   Strength: 2 mg
   Subjects: Normal healthy males and females, general population
   Additional Comments: Please see comment above.

Analytes to measure (in appropriate biological fluid): Repaglinide in plasma

Bioequivalence based on (90% CI): Repaglinide

Waiver request of in-vivo testing: 0.5 mg and 1 mg based on (i) acceptable bioequivalence studies on the 2 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.fda.gov/cder/ogd/index.htm. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.